SCHAFFNER Serial No. 10/541,359

August 4, 2009

AMENDMENT TO THE DRAWINGS

The attached replacement sheets of drawings include changes to original FIGS.

1 and 2. The replacement sheets which include FIGS. 1-3 replace the original sheets of

drawings.

Attachment: Replacement Sheets – FIGS. 1-3

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REMARKS

Favorable reconsideration and allowance of this application are requested.

1. Discussion of Amendments

By way of the amendment instructions above, the claims have been revised so as to emphasize the novel and patentable features of this invention. In essence, the nozzle structure has been incorporated into the amended version of claim 1 and the various flows clarified with respect to such structures. Claim 3 has thus been canceled as redundant.

In this regard, the claimed process has been clarified in the amended claims so to emphasize that a starch powder is fed to the nozzle into a space between the first and second cones such that the starch powder is discharged through the circular slot and contacts the particles of the emulsion discharged by the atomizer, wherein the particles are first coated with an adhesive layer of the starch powder followed by treatment with the hot air discharged from the hot air discharge channel surrounding the first cone. This attribute of the invention was described in the originally filed specification at page 1, penultimate and last lines and FIGS. 1 and 2 and the description thereof on pages 2-3 of the specification.

Claim 8 directed toward a patentably distinct invention non-elected for prosecution herein has been cancelled. Cancellation of claim 8 is however made without prejudice to the applicant's rights under 35 USC §121.

Claim 10 is new and represents the preferred ranges that were originally embedded in claim 2 but now canceled therefrom.

Thus, following entry of this amendment claims 1-2, 4-7 and 10 will remain pending herein for consideration.

2. Response to Drawing Objections

In response to the drawing objections raised by the Examiner, there are attached hereto replacement sheets of drawings comprised of FIGS. 1-3 which include appropriate reference numerals corresponding to the structures disclosed in the specification. The Substitute Specification submitted herewith thus has been conformed to such reference numerals.

Approval of the substitute drawings is therefore requested.

3. Response to 35 USC §112 Rejection

The amendment to claim 2 and the presentation of new claim 10 are believed to address the rejection advanced under 35 USC §112, second paragraph against original claim 2. Withdrawal of the same is requested.

4. Response to 35 USC §103(a) Rejection

The only issue remaining to be resolved in this application is the Examiner's rejection of prior claims 1-7 as allegedly "obvious" and hence unpatentable over Leuenberger (USP 5,668,183) in view of Skelbaek (WO 91/17821) and Christensen (USP 5,487,916). Applicant respectfully suggests that none of the applied publications is appropriate as a reference to reject the presently pending claims.

The present invention is related to a spray-drying process where the sprayed emulsion particles are collected in a bed of starch. The so-obtained products include particles comprising the matrix component and the fat-soluble substance which are covered by an adhesive layer of starch. The term "beadlets" as used in the claims and the specification refers to such particles. (See page 1, last two lines of specification.) Beadlets provide superior handling properties in that they are not dusty and possess good flowablity characteristics. However, the production of beadlets in such a manner

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is conventionally accompanied by the formation of deposits in the spray tower which requires an interruption of the spray-drying process for cleaning. The formation of deposits or agglomeration of beadlets in the tower is dependent on the humidity of the particles which itself is dependent on the particle size, wherein an increased humidity increases the formation of deposits.

The applicant has however discovered that the formation of deposits in a spray tower can be significantly suppressed or substantially avoided when a stream of cold air is introduced into the lower part of the spray tower, thus forming a fluidized bed which has a substantially lower temperature as compared to the temperature of the spray zone, whereupon the beadlets are discharged from the fluidized bed to a dryer to complete the drying process. Furthermore the applicant has found that it is also of particular importance that the aqueous emulsion of the fat-soluble substance(s) and the matrix material be fed to the tower in such manner that the emulsion is first distributed into emulsion droplets and then coated with starch particles (see FIG. 2) in order to avoid disadvantageous agglomerations of the beadlets afterwards and finally dried by hot air.

It is against this backdrop therefore that the presently claimed invention must be evaluated in light of the prior art.

In this regard, applicants note that none of the applied references disclose or even remotely suggest providing a spray nozzle of the variety defined in the pending claims herein so as to solve the problems as described above. In this regard, Leuenberger does not disclose the preparation of beadlets in industrial scale and does not discuss the problem of formation of deposits. All that Leuenberger discloses is that corn starch may be fluidized by means of silicic acid in a spray tank into which an emulsion may be sprayed so as to form particles enveloped by the starch. There is no disclosure or suggestion at all in Leuenberger of that starch particles may be contacted

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with emulsion particles in a spray zone with hot air so as to form an adhesive layer of starch thereon while cold air is introduced at the bottom of the spray tower.

As to this latter point, the Examiner turns to Christensen and asserts that cold air is introduced into the bottom of Christensen's shroud 9. Christensen however clearly does not introduce any *fluidization* air having a cold temperature into the bottom of the shroud 9. In direct contrast, the cooling (or heating) air of Christensen is introduced via conduit 14 at the top of the shroud 9 in convergence with the spray zone.

Moreover, Christensen does not teach of suggest at all the nozzle structure employed in the process of the invention and/or the manner in which atomized particles of an emulsion are coated with a starch powder as defined in the claims pending herein. In this regard, Christensen's processes involves coating a solid particle with an active ingredient in which the active substance is sprayed on a solid carrier particle. Since the solid carrier particle is already a dry solid, the problems solved by the present invention (i.e., preventing agglomerations and deposits in the spray tower) are not a concern.

The Skelbaek publication is even less pertinent that Leuenberger and Christensen. In this regard, while Skelbaek may in fact disclose various emulsion spray-drying temperatures, the deficiencies noted above with Leuenberger and Christensen would not be satisfied.

Therefore, withdrawal of the rejection advanced under 35 USC §103(a) based on Leuenberger, Christensen and Skelbaek is in order. Such favorable action is solicited.

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5. Fee Authorization

10.1 The Commissioner is hereby authorized to charge any <u>deficiency</u>, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140.

Respectfully submitted,

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